Remarks and Arguments

Claims 50 and 61 have been amended, and claims 58 and 60 cancelled. The remaining claims are 50-53, 56, 59 and 61-72.

35 U.S.C. §112 Rejection

Claims 50-53, 56, 58, and 60-72 were rejected under 35 U.S.C. §112 first paragraph as being enabling only for the treatment of an inflammatory condition located in the oral cavity. Without conceding the basis for or reasoning of the Examiner on this point, Applicant has amended claim 50 to further prosecution of the present claims in a manner that is clearly enabled by the specification for the reasons set forth below. Although the rejection was deemed final, Applicant believes the present amendment should be entered because it has clear support in the previously examined claims (see e.g., claims 58 or 60) and does not raise new issues that require further search or examination. Based on this amendment of independent claim 50, dependent claims 58 and 60 have been cancelled.

The Examiner's main concern is that the claimed treatment of *any* local inflammatory condition is not sufficiently enabled by the present specification and that only the use of enamel matrix proteins for treating inflammatory conditions associated with the oral cavity are enabled. In response, Applicant directs the Examiner's attention to the following. In his reasoning, the Examiner states that the present wording "treating a local inflammatory condition by topical application" would include treating conditions such as asthma, panceratitis or encephalopathy. The Examiner fails to elaborate on how the person skilled in the art would topically administer EMD to the lungs or the pancreas or the brain, though. To Applicant's best understanding, this line of reasoning is not realistic, as a person skilled in the art (e.g. a medical doctor) does of course know that you can not treat encephalopathy by topical administration of a drug.

As is well known in the medical field, "topical administration" pertains to a particular surface area, e.g., skin or a mucous membrane, as e.g. a topical anti-infective applied to a certain area of the skin, and affecting only the area to which it is applied. Typically, creams or ointments are applied topically.

What is more, the Examiner states that the present application only teaches examples of effects of EMD on inflammations in the oral cavity, resulting from either injection or trauma. This is actually not true, as example 13 demonstrates the effect of treating multiple patients having venous ulcers with EMD.

Venous ulcers are developed when blood pools in the veins of the lower legs. Due to the increased pressure and swelling, the skin of the legs leak tiny drops of plasma and as the capillaries burst under the high pressure, red blood cells discolor the skin, which in turn is easily broken by a scratch or bump. When this happens, the patient frequently develops local and inflamed leg skin wounds, so called venous stasis ulcers. Venous stasis ulcers are hard to treat and often turn chronic. Thus, Applicant clearly shows the use of EMD for treating inflammatory conditions of the skin.

The Examiner has acknowledged that Applicant clearly shows that inflammation in the mucosa of the oral cavity is treatable with EMD. As is well known to the person skilled in the art, the mucous membranes of the human body are very similar, as they are all derived from the same embryonic connective tissue, the endoderm, and share the same basic organ structure. It is e.g., common knowledge that you can generally readily replace administering a drug via the oral mucosa with administering the same formulation rectally, or as an aerosol to be inhaled. Therefore, the person skilled in the art would know that the results shown in the present examples are readily transferable to any other mucosa in the human or animal body.

Applicant does not agree with the assertion that the nature of the part presented by the Applicant is found to be unpredictable. The person skilled in the art would have had a very reasonable expectation of successfully preventing inflammatory conditions in the skin or mucosa of a patient after reading the present application. The experiments needed to confirm this would be regarded as standard laboratory or clinical practice.

Thus, Applicant respectfully asserts that the present claims which recite a method of treating a local inflammatory condition of skin or mucosa by topically administering the recited substance are fully enabled by the actual patient treatment procedure and data set forth in the specification describing treatment of the skin or mucosa, both within and outside the oral cavity.

The present amendment to claim 50 is also believed to address the Examiner's prior objection to the preamble of prior claim 50.

RECONSIDERATION

It is believed that all claims of the present application are now in condition for allowance.

Reconsideration of this application is respectfully requested. If the Examiner believes that a teleconference would expedite prosecution of the present application the Examiner is invited to call the Applicant's undersigned attorney at the Examiner's earliest convenience.

Any amendments or cancellation or submissions with respect to the claims herein is made without prejudice and is not an admission that said canceled or amended or otherwise affected subject matter is not patentable. Applicant reserves the right to pursue canceled or amended subject matter in one or more continuation, divisional or continuation-in-part applications.

To the extent that Applicant has not addressed one or more assertions of the Examiner because the foregoing response is sufficient, this is not an admission by Applicant as to the accuracy of such assertions.

Please grant any extensions of time required to enter this response and charge any fees in addition to fees submitted herewith that may be required to enter/allow this response and any accompanying papers to our deposit account 02-3038 and credit any overpayments thereto.

Respectfully submitted

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